

WEEK ENDING SEPTEMBER 13, 2013

OPP Weekly Activity Report

Highlights Include:

Page

- 2 Issuance of EUP for Aedes albopictus Mosquito Population Control Published in FR
- 2 Public Participation Comment Period Opens for New Soil Fumigant -- allyl isothiocyanate, a component of Oil of Mustard
- 2 Meetings held with Flumioxazin Registrant to Discuss Registration Review Data Call-In
- 3 Dimethomorph Final Work Plan Completed
- 3 PRD Converses with Nebraska Cattlemen's Association on Starlicide
- 4 National Nanotechnology Initiative -- focus on stakeholder perspectives on perception, assessment & management of potential risks of nanotech
- 4 Meeting with Fort Meade Civil Support Team
- 4 Master Plan Development at the Environmental Science Center
- 5 Conversations with a Beekeeper Webinar
- 6 Statistics Seminar Series
- 6 Conference Call on Metapath held to discuss alignment of the OECD harmonized templates on livestock studies
- 6 Meeting with Pyrethrins Joint Venture/Piperonyl Butoxide Task Force
- 7 Quarterly Incident Meeting with PMRA Held
- 7 Tolerances Established for Prometryn

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

Issuance of EUP for Aedes albopictus Mosquito Population Control Published in FR. On September 12, an Issuance of an Experimental Use Permit (EUP) for MosquitoMate, Inc. (EPA Reg. No. 89668-EUP-1) was published in the Federal Register. The EUP authorizes release of male Aedes albopictus containing the microbe Wolbachia pipientis ZAP strain. The approved EUP allows for release in California, Florida, and Kentucky during 2013 and 2014, and in New York during 2014 and 2015. A total of 4118 acres will be treated over the two year period. Decline of the Aedes albopictus mosquito population is expected because mating of these released mosquitoes with the naturally occurring females will result in non-viable eggs. Annual reports are required to monitor the decline in the mosquito population. Additional information can be found in docket EPA-HQ-OPP-2013-0254 available at www.regulations.gov. (Shanaz Bacchus, 308-8097)

Public Participation Comment Period Opens for New Soil Fumigant. On September 11, BPPD opened a 15-day public comment period for a manufacturing-use product (MP) and an end-use product (EP) that contain the biochemical active ingredient allyl isothiocyanate (AITC) at 99.8% and 96.3%, respectively. The MP, IR9804, is intended for formulation into end-use products for soil treatment/ fumigation. The EP, IRF135, is intended for use as a pre-plant soil treatment (soil fumigant) for insecticidal, fungicidal, herbicidal and nematicidal use. No residual activity of the EP is expected when applied as directed on the label, and the active ingredient and its degradates will dissipate prior to crop seeding. AITC, as a component of Oil of Mustard, was first registered by the Agency in 1962. The products are for use as part of an integrated pest management program to aid in reducing or controlling the damaging effects of soil borne pests and diseases. Documents supporting the proposed products are available for comment in docket EPA-HQ-OPP-2013-0658 until September 25, 2013. (Gina Burnett, 605-0513)

PESTICIDE RE-EVALUATION DIVISION

Meetings held with Flumioxazin Registrant to Discuss Registration Review Data Call-In (DCI). On September 10 and September 12, 2013, OPP held meetings with representatives of Valent Corporation and Sumitomo Chemical Company to discuss the status of data waiver requests they submitted in response to the February 2013 DCI for the Registration Review of Flumioxazin. The meeting on September 10 focused on the status of the ecological data requirements and staff attended from EFED, PRD, and RD. The meeting on September 12 focused on the status of the human health data requirements and staff from HED, PRD, and RD attended this meeting. Flumioxazin is an herbicide that is used for weed control in growing a variety of crops, including soybeans, almonds, grapes, and

ornamentals, as well as in aquatic settings and right-of-way areas. (Susan Bartow, 703-603-0065)

Status of Issuing GDCIs. During the period from September 5 until September 12, 2013, PRD issued a Generic Data Call-In (GDCI) for 10 cases: Bifenazate, Chlorsulfuron, Clodinafop-propargyl, Foramsulfuron, Iprodione, Kresoxim-methyl, Prohexadione calcium, Hydramethylnon, Sulfometuron-methyl, and TPTH. Also during Fiscal Year 2013, PRD issued 87 GDCI packages: 83 individual case GDCIs and 4 supplemental-GDCIs (to accommodate added studies for individual cases) of registration review. (Joseph Nevola, 308-8037; Meredith Scott 308-0049; Shirley Miller 308-0138)

<u>Dimethomorph Final Work Plan (FWP) Completed.</u> On September 3, 2013, PRD signed the Dimethomorph Final Work Plan for Registration Review. Dimethomorph is a systemic morpholine fungicide developed to control downy mildews, late blights, and crown and root rots on grapes, potatoes, tomatoes, and other vegetables. Dimethomorph is registered for use on various non-agricultural sites, such as forest trees and ornamental plants, but there are no registered residential uses. The Agency received comments from FESTF and the dimethomorph technical registrant during the 60-day public comment period on the Preliminary Work Plan. The comments resulted in minor changes to the anticipated ecological and environmental fate data requirements. The FWP will be posted in the registration review docket (EPA-HQ-OPP-2013-0045). (Monica Wait, 347-8019)

PRD Converses with Nebraska Cattlemen's Association on Starlicide. On September 12, 2013, PRD responded to questions from the Nebraska Cattlemen's Association regarding the registration review of Starlicide. Starlicide is a restricteduse Avicide used to control certain bird species in a variety of use sites, including livestock and poultry feedlots, Federal and State wildlife refuges and protected areas, gull colonies in coastal areas, and bird staging areas and roosting sites. The Nebraska Cattlemen Association received a number of calls that prompted interest in the Starlicide re-evaluation process about significant increases in the cost of its products. In addition to questions about the reevaluation process, the Association asked about the possibility of data waivers or other considerations given the limited usage of this pesticide. PRD explained that OPP was working with the primary registrant, USDA APHIS, since the beginning of its 2011 registration review to limit the number of data requirements through the clarification of label language. Finally, PRD provided a contact at APHIS for additional questions on the Starlicide surcharge that APHIS implemented to fund the required studies. (Starlicide Docket # EPA-HQ-OPP-2011-0696). (Monica Wait, 703-347-8019)

ANTIMICROBIALS DIVISION

National Nanotechnology Initiative (NNI). On September 10-11, 2013 AD staff attended the NNI workshop that focused on stakeholder perspectives on perception, assessment, and management of the potential risks of nanotechnology. The workshop speakers offered viewpoints from industry, consumers, labor, academia, and NGOs. Of note to OPP, Mike Hansen of the Consumers Union was encouraged by EPA's proposal to use the 6(a)(2) reporting obligations for nanopesticides and Jennifer Sass of NRDC presented their assessment that silver and nanosilver are hazardous while there was not enough information on the pesticide HeiQ AGS-20 (Reg. No. 85249-1) to draw a conclusion on hazard. Industry cited the lack of EPA regulatory guidance as the key uncertainty affecting the decision to manufacture nanomaterial based products in the US and called for the establishment of testing guidelines, a repository for information, a clear regulatory roadmap, and a liaison. (Jed Costanza 703-347-0204)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

Meeting with Fort Meade Civil Support Team. In response to a request from the Office of Emergency Management, staff and management from the Environmental Science Center along with officials from the Office of Emergency Management met with the representatives from the Ft. Meade Civil Support Team (CTS). The CTS provides rapid response capability and analytical support during emergency situations. The ESC does not have a high hazard receipt facility to manage unknown samples. The CTS was approached by the Agency to provide triage of unknown samples to rule out explosives, high level chemical warfare agents, radiological, and certain biological pathogens of unknown samples before receipt by the ESC analytical teams. EPA provided an overview of the Agency's Environmental Response Laboratory Network (ERLN). The CTS indicated that they could provide services if the samples were infrequent without a formal agreement or IA. If the number of samples exceeds threshold numbers, there would need to be a formal agreement in place to cover the cost of supplies, materials, and analytical support. The CTS is going to familiarize themselves with the Agency's ERLN and speak with higher level officials in their chain of command. (Mark Hartman, 308-0734 and Susan Lawrence, 410-305-2954)

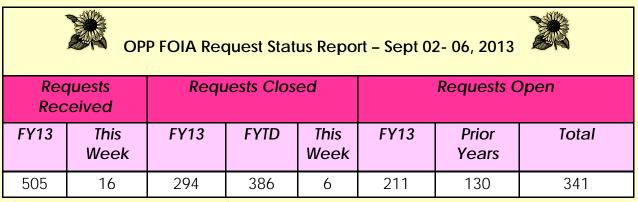
Master Plan Development at the Environmental Science Center. A team of architects, engineers, and facility planners from the EPA Office of Administration and Resource Management (OARM) and the Smith Group (contractors) are on site at the ESC this week collecting information to develop a master plan for the facility. A master plan provides the footprint for future facility modifications based on five and ten year projections of work currently being done and projected to be done in the future at the facility. OARM provided an overview of the process

for collecting information via tours and interviews with facility personnel and the scientific staff at the ESC. OPP provided an overview of the laboratory resources, clients, and services to the group on Wednesday, September 11th. The group conducted in depth tours of the OPP laboratory wings on Wednesday as well. The information that is being collected overlaps in certain areas with information collected under the Laboratory Infrastructure Data Call. (Mark Hartman, 308-0734; Susan Lawrence, 410-305-2954; Paul Golden, 410-305-2960)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

<u>CSIB assists the Human Studies Review Board</u>: CSIB worked with the OPP/IO to create and upload to the EPA Portal the agency's presentations to the Board for the October meeting. The Human Studies Review Board (HSRB) is a Federal advisory committee operating under the Federal Advisory Committee Act (FACA) that provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research. The HSRB reports to the EPA Administrator through <u>EPA's Science Advisor</u>. If you have a need for any collaboration support services, please email <u>CollaborationSupport@epa.gov</u> and a member of the staff will contact you. (Troy Stewart, 703-308-2738)

CSIB Provides Video Conferencing Support: CSIB worked with the Antimicrobial Division (AD) staff to schedule and execute a video conference with GE Healthcare in the United Kingdom. The Registrant wanted to meet with the Agency scientists and regulatory staff to clarify the process. CSIB provides collaboration support services to OPP including webinar support, Portal project management tools, and video conferencing support. If you have a need for any of the aforementioned services, please email CollaborationSupport@epa.gov and a member of the staff will contact you. (Elton Harrison, 703-305-5366)



(Ana Espinoza, 703-347-0102)

ENVIRONMENTAL FATE & EFFECTS DIVISION

<u>Conversations with a Beekeeper Webinar</u>. On the evening of September 10, EFED staff presented a webinar to the American Beekeeping Federation (ABF)

on ecological incident reporting and how these data are used by OPP to support its risk assessment process for pesticides. This was the fourth webinar presented by EFED to the ABF as part of a series entitled "Conversations with a Beekeeper." Although participation in the webinar series has historically been limited to ABF members, their Board of Directors felt the subject matter was important enough to open the webinar to the general public; approximately 76 individuals signed up for the evening webinar. Questions from the audience included concerns as to what criteria are used to classify a bee kill incident as "major" or "minor," the extent to which bee kill incident reports are aggregated as "minor" incidents by industry or reported individually, whether state lead agencies are required to report incidents to EPA, and the percentage of bee kill incident reports associated with non-agricultural uses. Broader questions from the audience included whether EPA evaluates risk from formulated products and whether testing guidelines have been developed for examining the effects of pesticides on larval bees. (Tom Steeger, 703-305-5444).

<u>Statistics Seminar Series</u>. On September 11, EFED's Statistical Tech Team held a webinar on Descriptive and Inferential Statistics and Significant Figures. This webinar is the first in a series of seven webinars that EFED is planning to present as a refresher or learning tool on the fundamental methods of statistical analysis. Topics for the webinars range from statistical distributions and experimental design through regression analysis and hypothesis testing. (Justin Housenger, 305-6060).

HEALTH EFFECTS DIVISION

Conference Call on Metapath: Christine Olinger, HED, along with ORD/Duluth and ORD/Athens, held a conference call with OECD staff to discuss alignment of the OECD harmonized templates on livestock studies with the DER Composer and the OPP/PMRA templates. We discussed the utility of the DER composer (associated with Metapath) for entering data into the templates along with similarities and minor differences between the OECD templates and the NAFTA templates. OECD Staff plan to try the DER composer prior to our next discussion on further harmonization of templates. (Christine Olinger 305-5406)

Py/PBO Registrant Meeting: Representatives from HED, PRD, and EFED met with the Pyrethrins Joint Venture/Piperonyl Butoxide Task Force for an update on the submission of studies to support reregistration. There were a number of questions presented to HED at the meeting concerning the residue program being put forward by the registrants. These questions included the timing of studies for submission, the preparation of tolerance petitions, dietary assessment work, and the retention of field samples. HED recommended that the Task Force residue program compile as many of the tolerance petitions into bulk submissions whenever possible to limit the preparation of repetitive risk assessments. In

addition, HED explained the process for completing dietary assessments and recommended that the retention of samples could follow demonstrated timeframes for acceptable storage stability. (Peter Savoia, 308-8794)

HED ChemSAC Review of Three Crop Group Petitions: Dr. Bernard Schneider presented his analysis of three crop group petitions for approval by ChemSAC and Canada, PMRA. The three crop groups are: Leafy Vegetable crop group amendments, the Brassica leafy crop group amendments, and a new crop group 22 for Stalk, stem, and leaf petiole Vegetables group. ChemSAC and PMRA approved the new Stalk, stem, and leaf petiole vegetables group 22 and revised Brassica Head and stem group 5. The leafy vegetable group 4 was approved to combine two subgroups, one for leafy vegetables and one for Brassica leafy vegetables. Further discussion about the leaves of root and tuber vegetables will be discussed at the next ChemSAC meeting. (Bernard Schneider, 703-305-5555)

<u>Quarterly Incident Meeting with PMRA Held:</u> OPP staff from several divisions including HED, PRD, EFED and ITRMD held a quarterly meeting with PMRA to discuss incident data activities of mutual interest. Among topics discussed were updates to the SENSOR-Pesticides program, Spot-On updates, and upcoming PMRA/OPP joint reviews of chemicals imadicloprid and glyphosate. (Elizabeth Evans, 305-7891)

REGISTRATION DIVISION

Tolerances Established for Prometryn On September 11, 2013, the Federal Register published a final rule, which established tolerances for residues of the herbicide prometryn in or on succulent snap bean, fresh and dried dillweed, and dill oil. The dillweed tolerances supersede the established tolerance with regional registrations for dill. Prometryn is a substituted thiomethyl triazine herbicide that is registered in the United States for use on a number of agricultural crops. It may be applied either before or after weeds emerge for the control of most annual broadleaf weeds and grasses. Syngenta Crop Protection owns the pesticide product labeling and The Interregional Research Project No. 4 (IR-4) requested the tolerances associated with this action. (Laura Nollen, 703/305-7390)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Branch o	ıranted:	Number	Code		Date
Propiconazole	Albaugh Inc.	42750-252	R300	9/16/2013	9/10/2013
1 Topiconazoro	/ wedagii iiio.			, 703/305-7269	77 107 20 10
Sulfur	NuFarm Americas, Inc.	55146-140	R331	9/11/2013	9/10/2013
Juliui	ival all it will cheas, inc.			703/305-9096	77 107 2013
Myclobutanil	Prime Source, LLC	89442-15	R300	9/23/2013	9/9/2013
Wyclobatariii	THITIC SOURCE, LEC			703/347-8961	77 77 2013
The Herbicide Branch g	rantod:	31	iaurita miii,	703/347-6901	
Topramezone	BASF Corporation	7969-339	R170	8/23/2013	9/10/2013
торгаттегопе	BASE Corporation				9/10/2013
A 1 1 1	I I avvalana I D. I. I. I.			ı, 703/347-8072	0/10/0010
Acetochlor	Loveland Products, Inc.	34704-1081 34704-1082	R300	9/16/2013	9/10/2013
			/ Hartman	703/347-0189	
2,4-D, dimethylamine	NuFarm Americas, Inc.	55146-131	R331	9/10/2013	9/9/2013
salt	ival all it will cheas, inc.	33140 131	11331	77 107 2013	77 77 2013
		Dian	ne Morgan	, 703/305-6217	1
Glyphosate	NewAgco, Inc.	86794-3	R310	10/18/2013	9/11/2013
isopropylammonium	<u> </u>				
Prometryn	Syngenta Crop	100-542	R170	10/16/2013	9/12/2013
	Protection, LLC		1 0 111	700//05 0700	
			idy Ondish,	703/605-0723	Т
2,4-D, 2-ethylhexyl	United Suppliers, Inc.	33270-20	R300	9/23/2013	9/9/2013
ester 2,4-D, dimethylamine		33270-21			
salt		33270-21			
		Gran	nt Rowland,	703/347-0254	1
The Insecticide Branch	granted:				
Bifenthrin	FMC Corporation	279-3281	R340	9/9/2013	9/9/2013
	Agricultural Products				
	Group				
	1			r, 703/305-7460	
Zeta-Cypermethrin	FMC Corporation	279-3347	R340	9/16/2013	9/9/2013
	Agricultural Products				
	Group		Linda Do	Luise, 703/305-	5428
The Insecticide-Rodent	icide Branch granted		LINGA DE	Edisc, 703/303-	J-720
Diphacinone	Scimetrics, Ltd. Corp	72500-23	R334	8/4/2014	9/9/2013
2.p. ideli ione	Confiction, Etd. Corp			w, 703/347-023	

R170 – Additional food use; R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix; R310 – New end-use or manufacturing use product; requires review of data package within RD; includes reviews and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy; R331 – New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only. Selective data citation. (2) (3); R334 – New product; MUP or End use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2) (3); and R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient). Selective data citation. (2) (3).